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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,150	07/18/2003	Anne Marie Heegaard	2815-0444PUS1	5193
2292 7590 06/09/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
DUNSTON, JENNIFER ANN				
ART UNIT		PAPER NUMBER		
1636				
NOTIFICATION DATE		DELIVERY MODE		
06/09/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

### Office Action Summary

**Application No.**

10/623,150

**Applicant(s)**

HEEGAARD ET AL.

**Examiner**

JENNIFER DUNSTON

**Art Unit**

1636

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to the amendment, filed 3/5/2009, in which claims 18 and 28 were canceled, and claims 9, 21 and 22 were amended. Claims 9, 21 and 22 are pending and under consideration.

Applicant's arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn. **This action is FINAL.**

#### ***Response to Arguments - Claim Objections***

The objection of claims 18 and 28 is moot in view of Applicant's cancellation of the claims in the reply filed 3/5/2009.

The objection of claim 9 has been withdrawn in view of Applicant's amendment to the claim in the reply filed 3/5/2009.

#### ***Response to Arguments - Double Patenting***

The rejection of claims 18 and 28 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 59 and 60 of copending Application No. 10/622,377 is moot in view of Applicant's cancellation of the claims.

The rejection of claims 9, 21 and 22 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 59 and 60 of copending Application No. 10/622,377, has been withdrawn in view of the proper terminal disclaimer filed in Application No. 10/622,377.

***Response to Arguments - 35 USC § 102***

The rejection of claims 18 and 28 under 35 U.S.C. 102(c) as being anticipated by Maher et al is moot in view of Applicant's cancellation of the claims in the reply filed 3/5/2009.

The rejection of claims 9, 21 and 22 under 35 U.S.C. 102(c) as being anticipated by Maher et al has been withdrawn in view of Applicant's amendment to the claims in the reply filed 3/5/2009. Maher et al does not teach the step of measuring the efficacy of the compound in treating osteoporosis, osteolytic cancer invasion, or Paget's disease of bone, however, removal of the new matter by claims amendment may result in reinstitution of new withdrawn rejections..

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

In the reply filed 3/5/2009, independent claim 9 was amended to include the step of "further measuring the efficacy of any chemical compound, which is identified as having the ability to block the CIC-7 chloride channel, in treating osteoporosis, osteolytic cancer invasion,

or Paget's disease of bone." The claim now requires the further step of taking the compounds that have measured ability in blocking the ClC-7 chloride channel and further measuring the efficacy of the compound in treating osteoporosis, osteolytic cancer invasion or Paget's disease of the bone.

The specification notes that "the invention relates to a method for screening a chemical compound for activity in the treatment, prevention or alleviation of an osteoclast related bone disease in a subject" (page 2, 7<sup>th</sup> paragraph). To obtain this objective of the invention, the specification discloses the following steps (i) providing a test cell comprising one or more chloride channels of the ClC family; (ii) subjecting the test cell to the action of the chemical compound; and (iii) measuring the ability of the compound to block the selected chloride channels (page 3, 3<sup>rd</sup> paragraph). The specification envisions measuring the ability of the compound to block a ClC-7 channel by the method disclosed in example 4 (e.g., page 5, 5<sup>th</sup> paragraph) or by a multitude of techniques known in the art (e.g., page 7, 4<sup>th</sup>-7<sup>th</sup> paragraphs). Example 3 describes patch clamp screening for compounds, and example 4 describes Northern blot for ClC-type channels. While the specification provides support for measuring the ability of a compound to block a ClC-7 channel in a test cell, the specification does not provide support for further measuring the efficacy of the compound in treating osteoporosis, osteolytic cancer invasion or Paget's disease of the bone. The specification does not envision specific method steps that would provide a measure of therapeutic efficacy, such as administration of the compound to a cell culture model or animal model of osteoporosis, osteolytic cancer invasion or Paget's disease of bone. The method steps disclosed in the specification do not result in the measurement of efficacy.

The original specification, drawings and claims were thoroughly reviewed and no support could be found for the amendment. Accordingly, the amendment is a departure from the specification and claims as originally filed, and Applicant has provided do not provide passages that provide support.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.  
Examiner  
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/JD/

/ Christopher S. F. Low /  
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